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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SUPERVALU, INC.;** **DBA SAVON.COM #5805** **2510 El Camino Real, Suite A** **Carlsbad, CA 92008** **Pharmacy License No. PHY 48198** **PERRY WAYNE BROWN** **3299 Integrity Way** **Fallbrook, CA 92028** **Pharmacist License No. RPH 32935** Respondents.	Case No. 4143 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about December 19, 2006, the Board issued Pharmacy License Number PHY 48189 to SuperValu, Inc., doing business as Savon.Com #5805 (Respondent Savon.Com). On

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December 19, 2006, Perry Wayne Brown associated as the Pharmacist-In-Charge of Respondent SavOn.com. The Pharmacy License was in full force and effect at all times relevant to the charges brought herein, expired on June 1, 2013, and was cancelled.

3. On or about August 10, 1979, the Board issued Pharmacist License Number RPH 32935 to Perry Wayne Brown (Respondent Brown). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2015, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 4300 of the Code states in relevant part:

> (a) Every license issued may be suspended or revoked.
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> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
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> (1) Suspending judgment.
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> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
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> . . .
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> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

6. Section 4300.1 of the Code, effective January 1, 2013, states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or

proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY AUTHORITIES

7. Section 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

8. Section 4076 of the Code states in relevant part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

. . . .

9. Section 4081 of the Code states in relevant part:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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10. Section 4105 of the Code states in relevant part:

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(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

. . . .

11. Section 4110 of the Code states in relevant part:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

. . . .

12. Section 4169 of the Code states in relevant part:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

. . . .

13. Section 4301 of the Code states in relevant part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

. . .

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

. . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

. . . .

14. Health and Safety Code section 11165 effective January 1, 2010 to December 31, 2011, stated in relevant part:

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

. . .

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

15. Health and Safety Code section 11179 states:

A person who fills a prescription shall keep it on file for at least three years from the date of filling it.

16. Health and Safety Code section 108695 states:

To the extent that the requirements of this chapter are identical with the federal act, all regulations and any amendments to the regulations adopted pursuant to the federal act, that are in effect on January 1, 1978, or that are adopted on or after that date, shall be the poison prevention packaging regulations of this state.

REGULATIONS

17. California Code of Regulations (CCR), title 16, section 1707.2, states in relevant part:

. . .

(b) . . .

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

. . . .

18. CCR, title 16, section 1717, states in relevant part:

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

. . . .

19. CCR, title 16, section 1783, states in relevant part:

. . .

(d) A manufacturer or wholesaler shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or

devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the mermit for the authorized person; and (2) on an account bearing the name of the permittee.

20. Code of Federal Regulations (CFR), title 16, section 1701.1, states in relevant part:

(a) In order to assist manufacturers of prescription drugs in discharging their responsibilities under the act concerning such drugs that are distributed to pharmacies, the Consumer Product Safety Commission has codified this statement of its policy concerning which prescription drug packages supplied by manufacturers to pharmacies must comply with the "special" (child-resistant) packaging requirements contained in 16 CFR 1700.15.

(b) Manufacturers of prescription drugs may package such drugs for distribution to pharmacies in different types of packages, depending on whether the manufacturer intends that the package will be the one in which the drug is ultimately given to the consumer or whether it is intended that the pharmacist will repackage the drug before it is dispensed to the consumer. If the drug is supplied in a bulk package from which individual prescriptions are intended to be repackaged by the pharmacist, the manufacturer need not utilize special packaging. However, the Commission interprets the provision of the act as requiring that all prescription drugs subject to a special packaging standard that are distributed to pharmacies shall be in special packaging if the immediate package in which the drugs are distributed by the manufacturer is intended to be the package in which the drugs are dispensed to the consumer. Examples of such packages include mnemonic dispensing devices; dropper bottles; packages with "tear off" labels; packages which incorporate ancillary instructions for consumer handling, storage, or use on permanently affixed portions of their labels; and products intended to be reconstituted in their original containers. The Commission believes that this interpretation is necessary in order to insure that the pharmacist will actually dispense the drug in the proper package. If the pharmacist receives a request from the consumer or an order from the prescribing medical practitioner for conventional (noncomplying) packaging, section 4(b) of the act permits the pharmacist to convert the package to conventional packaging or repackage the drug in conventional packaging.

(c) Manufacturers should also note that section 4(a) of the act (which allows a product to be marketed in noncomplying packaging of a single size under certain circumstances) does not apply to prescription drugs subject to section 4(b) of the act. Thus, since the section 4(a) single-size exemption for over-the-counter drugs and other household substances does not apply to prescription drugs, every unit of a prescription drug subject to a special packaging standard which is distributed to a pharmacy in a package intended by the manufacturer to be dispensed to a consumer shall be in special packaging.

(d) Nothing in this statement of policy and interpretation should be interpreted as relieving the pharmacist of the responsibility of insuring that all prescription drugs subject to a special packaging standard are dispensed to the consumer in special packaging unless otherwise ordered by the prescribing practitioner or otherwise requested by the consumer.

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21. CFR, title 21, section 1301.11 states in relevant part:

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

. . . .

22. CFR, title 21, section 1301.12 states in relevant part:

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

. . . .

23. CFR, title 21, section 1304.22 states in relevant part:

Each person registered or authorized (by § 1301.13(e) or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

(a) Records for manufacturers. Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

. . .

(2) For each controlled substance in finished form,

. . .

(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;

. . . .

24. CFR, title 21, section 1305.13 states in relevant part:

(a) A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

. . . .

25. CFR, title 21, section 1306.22 states in relevant part:

. . .

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

(1) The name and dosage form of the controlled substance.

(2) The date filled or refilled.

(3) The quantity dispensed.

(4) The initials of the dispensing pharmacist for each refill.

(5) The total number of refills for that prescription.

(d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record, it shall be deemed that the full face amount of the prescription has been dispensed.

(e) The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original paper prescription or annotates the electronic prescription record with the date, quantity of refill, number of additional refills authorized, and initials the paper prescription or annotates the electronic prescription record showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

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(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized application must also provide online retrieval (via computer monitor or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized application shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized application employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator

requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized application experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again.

(g) When filing refill information for original paper, fax, or oral prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two applications described in paragraphs (a) through (e) or (f) of this section.

(h) When filing refill information for electronic prescriptions, a pharmacy must use an application that meets the requirements of part 1311 of this chapter.

COSTS

26. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FACTS

November 16, 2010 Inspection/Investigation

27. On September 10, 2010, the Board received a complaint alleging Respondent SavOn.com had multiple questionable dispensing procedures. On October 19, 2010, the Board received a second complaint which alleged essentially the same questionable practices.

28. On November 16, 2010, the Board's inspectors conducted a routine inspection and complaint investigation of Respondent SavOn.com located at 2510 El Camino Real, Suite A, in Carlsbad, California. Respondent Brown was present, together with a pharmacist, five pharmacy technicians, an IT specialist, a shipping specialist for "DailyMed California," the operations manager from Indianapolis for "DailyMed California," the Vice President of SuperValu, Inc., and the Vice President of Pharmacy Operations for DailyMed Pharmacy (Non-Resident Pharmacy License NRP 956, cancelled); all with the same address as Respondent SavOn.com.

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29. During the course of the inspection, the Board's investigators learned that two pharmacies operated within Respondent Savon.com's licensed premise in Carlsbad, California: Respondent SavOn.com and "DailyMed California," (also known as DailyMed Dedicated Facility "DMDF"). DailyMed California has never been licensed by the Board as either a pharmacy or wholesaler. DailyMed California was also never registered with the Federal Drug Enforcement Agency (DEA).

30. On or about November 9, 2009, SuperValu Inc., the owners of Respondent Savon.com, and Arcadia Resources, Inc., dba Arcadia HealthCare, one of the partners in DailyMed Pharmacy, entered into an agreement to provide prescription drug services, to bill, and to adjudicate claims for WellPoint's California Medicaid (Medi-Cal) member patients. Under the terms of the agreement, WellPoint's California Medicaid (Medi-Cal) member patients' prescriptions were processed and stored at DailyMed Pharmacy in Indianapolis, Indiana. Respondent SavOn.com authorized DailyMed Pharmacy to bill California Medicaid (Medi-Cal) member patients' prescription drugs using Respondent Savon.com's Medi-Cal Provider Number, and National Counsel for Prescription Drug Programs (NCPDP) Provider Identification Number,[1] as well as the NCPDP Number for SavOn #6741 located in Poway. Under the agreement, DailyMed Pharmacy in Indianapolis was billed for the pharmaceutical drugs shipped to Respondent SavOn.com's licensed location in Carlsbad, California. Respondent SaveOn.com transferred the pharmaceutical drugs to DailyMed California (also known as DailyMed Dedicated Facility, "DMDF"), the unlicensed pharmacy operating inside Respondent SavOn.com. DailyMed California then dispensed the pharmaceutical drugs to WellPoint's California Medicaid (Medi-Cal) member patients by: (1) downloading the patients' prescription data from DailyMed in Indianapolis onto computers maintained at Respondent SavOn.com's licensed facility; (2) printing out prescription labels in the name "DailyMed California;" (3) placing the "DailyMed

[1] The NCPDP Provider Identification number was developed over 25 years ago to provide pharmacies with a unique, national identifier that would assist pharmacies in their interactions with pharmacy payers and claims processors. The NCPDP Provider ID is a seven-digit numbering system that is assigned to every licensed pharmacy and qualified Non-Pharmacy Dispensing Sites (NPDS) in the United States.

California" labels on containers packaged with the pharmaceutical drugs that had been transferred from Respondent SavOn.com to "DailyMed California;" and (4) once packaged, shipping the pharmaceutical drugs from Respondent SavOn.com's licensed facility to the Medi-Cal member patients using DailyMed Pharmacy's name on the shipping packages.

31. Beginning in or about January 2010, and continuing until the time of the inspection on November 16, 2010, Respondent Brown served as the Pharmacist-In-Charge of Respondent SavOn.com and as the General Manager ("Rx CA") of DailyMed California, the unlicensed pharmacy. The two pharmacies operated at Respondent SavOn.com's licensed facility as follows:

(a) Respondent SavOn.com and DailyMed California, the unlicensed pharmacy, maintained separate computer systems for the two pharmacies inside Respondent SavOn.com's licensed facility;

(b) Respondent SavOn.com and DailyMed California maintained separate labels for the prescriptions dispensed by the two pharmacies;

(c) Respondent SavOn.com and DailyMed California maintained separate inventories in the two pharmacies;

(d) DailyMed California did not have a pharmacy license or a DEA registration, and therefore did not have the required DEA 222 forms to fill out to purchase Schedule II controlled substances. Respondents SavOn.com and Brown authorized DailyMed California and/or DailyMed Pharmacy to establish a line of credit and order dangerous drugs and controlled substances for DailyMed Pharmacy from five different wholesalers using Respondent SavOn.com's pharmacy license and DEA number. These pharmaceutical drugs were shipped to Respondent SavOn.com and billed to DailyMed Pharmacy in Indianapolis and its subsidiaries. Respondents Brown and SavOn.com transferred these pharmaceutical drugss to DailyMed California without any accompanying DEA 222 form authorizing the transfers;

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(e) Respondent SavOn.com authorized DailyMed California to dispense the dangerous drugs and controlled substances to patients in DailyMed California's labeled prescription containers from Respondent SavOn.com's licensed facility;

(f) The prescriptions that DailyMed California processed at Respondent SavOn.com's pharmacy were entered and retained at DailyMed Pharmacy in Indianapolis, and not in California;

(g) Respondents SavOn.com and Brown endorsed DEA 222 forms without the quantity received and the date;

(h) The CURES reporting by Respondent SavOn.com did not reflect the pharmaceutical drugs dispensed by DailyMed California at Respondent Savon.com's facility;

(i) Respondent Savon.com received dangerous drugs and controlled substances in the shipping and receiving section of Respondent SavOn.com's facility, transferred most of these dangerous drugs and controlled substances to DailyMed California, who then shipped out the dangerous drugs and controlled substances to fill mail order prescriptions from Respondent SavOn.com's shipping and receiving location;

(j) Respondent SavOn.com did not maintain at its licensed facility the hard-copy printouts for the refill prescriptions dispensed for Schedule III and Schedule IV controlled substances for either Respondent SavOn.com or DailyMed California, the unlicensed pharmacy;

(k) Respondents Brown and SavOn.com did not document, by printing, verifying and/or signing the record for the prescriptions they refilled within 72 hours;

(l) Respondent SavOn.com and Brown failed to maintain original prescriptions for the Schedule II controlled substances dispensed through DailyMed California, the unlicensed pharmacy, at Respondent SaveOn.com's licensed facility.

32. On March 8, 2011, the Board issued a cease and desist notice to DailyMed California under Business and Professions Code section 4110 to stop conducting, operating, practicing, or acting as a pharmacy without being licensed by the Board in the same suite as Respondent Savon.com located at 2510 El Camino Real, Suite A in Carlsbad.

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33. On March 8, 2011, the Board issued a written notice of violation to Respondent Savon.com for allowing DailyMed California to operate a pharmacy within Suite A at 2510 El Camino Real, Suite A in Carlsbad when only one site license is permitted per premise.

June 14, 2011 Inspection/Investigation

34. On March 24, 2011, the Board received a complaint from a pharmacist alleging DailyMed Pharmacy was using salesmen to enroll his pharmacy's patients into its pharmacy bubble packing process.

35. On June 14, 2011, the Board conducted another compliance inspection and complaint investigation of Respondent SavOn.com located at 2510 El Camino Real, Suite A in Carlsbad, California together with an investigator from the California Department of Health Care Services, and an agent from the Federal Bureau of Narcotic Enforcement.

36. On June 14, 2011, at the time of the inspection/investigation, Respondent Brown continued to authorize the original prescription records for Schedule III, Schedule IV, and Schedule V controlled substance prescriptions dispensed by Respondent SavOn.com to be maintained by DailyMed Pharmacy in Indianapolis, and not in California where the drugs were dispensed.

37. From January 1, 2010 to May 16, 2011, Respondent Brown and Respondent SavOn.com failed to submit CURES reporting for either the prescriptions processed by DailyMed Pharmacy in Indianapolis or the controlled substances dispensed at Respondent SavOn.com.

38. On June 14, 2011, Respondent Brown and Respondent SavOn.com did not include a written notice to patients with all prescriptions dispensed of their right to consultation, and also did not provide a consultation telephone number for a Respondent SavOn.com pharmacist in Carlsbad, California with ready access to the patients' record.

39. On June 14, 2011, Respondent Brown and Respondent SavOn.com dispensed prescriptions in boxed containers with shipping labels containing the name DailyMed California, and with prescription strip labels containing DailyMed Pharmacy's name with DailyMed California's address within Respondent SavOn.com.

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40. On June 14, 2011, Respondent Brown and Respondent SavOn.com dispensed a prescription by affixing a prescription label on a box of Cyclosporin 100 mg capsules for a patient that identified the manufacturer as Watson but was manually changed to Teva, without the capsule identification also being changed. The resultant prescription label identified the capsules as oblong shaped, off-white in color, inscribed PA20 from Watson, but the label was affixed to the Teva box of Cyclosporin 200 mg capsules which identified the capsules as an oblong shaped, brown capsule, inscribed with a Watson logo and 100 mg.

41. On June 14, 2011, Respondent Brown and Respondent SavOn.com used a dispensing machine to package prescriptions in non-child resistant packaging that were sent to patients with a "New Patient Acknowledgment Form," without a "Notice of Non-Child Resistant Packaging" form, without the patient requesting non-child proof packaging, and without the patient's signed authorization to send non-child resistant packaging prior to dispensing.

42. On June 14, 2011, Respondent SavOn.com processed a prescription by dispensing the drugs at Respondent SavOn.com's facility in Carlsbad, California, but maintained the patient's original prescription records, which included Schedule III and Schedule IV controlled substances, at DailyMed Pharmacy in Indianapolis, Indiana.

43. On June 14, 2011, Respondent SavOn.com and Respondent Brown dispensed prescriptions with the name "DailyMed California" on the boxed containers, shipping labels, and the name "DailyMed Carlsbad" on the prescription strip labels.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Dispensing Prescriptions in Illegal Containers)

44. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) in that on November 16, 2010, Respondents dispensed prescriptions in prescription containers in the name of DailyMed California in violation of Code section 4076(a)(6), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

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SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Maintaining Prescription Records Out-Of-State)

45. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that on November 15, 2010 and June 14, 2011, Respondents failed to maintain in California the hard copy, original prescription records for prescriptions, including Schedule III and Schedule IV controlled substances that Respondents SavOn.com and Brown dispensed to DailyMed California patients, in violation of Code section 4081, subdivision (a) and section 4105, subdivision (d), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Failing to Properly Verify and Maintain Prescription Records)

46. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that on November 15, 2010, Respondents failed to properly print out, verify, date, sign and maintain prescription records for refilled Schedule III and Schedule IV controlled substances in violation of CFR, title 21, 1306.22, as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Aiding and Abetting the Illegal Wholesaling of Dangerous Drugs)

47. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that Respondents aided and abetted the illegal wholesaling of dangerous drugs in violation of CCR, title 16, section 1783, subdivision (d), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

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FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Failure to Maintain Original Prescriptions for Controlled Substances)

48. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (j), in that Respondents failed to maintain original prescriptions for Schedule II controlled substances for at least 3 years from the date of filling for prescription in violation of Health and Safety Code section 11179, as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Failure to Submit CURES Data on Controlled Substances Dispensed)

49. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that between January 1, 2010 to May 16, 2011, Respondents failed to submit CURES data for the Schedule II, Schedule III and Schedule IV controlled substances dispensed in violation of Health and Safety Code Section 11165(d), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Authorizing the Dispensing of Controlled Substances Without a DEA Registration)

50. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that on November 16, 2010, Respondents aided and abetted DailyMed California to dispense controlled substances at Respondent SavOn.com's licensed facility without a separate DEA registration in violation of CFR, title 21, section 1301.11, subdivision (a) and section 1301.12, subdivision (a), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

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EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – the Operation of an Unlicensed Pharmacy)

51. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for the operation of DailyMed California, an unlicensed pharmacy, at Respondent SavOn.com's licensed pharmacy location in violation of Code Section 4110, subdivision (a), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Failing to Advise Patients of their Right to a Pharmacist Consultation)

52. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that Respondents shipped prescriptions without written notice informing patients of their right to consultation from a pharmacist who had ready access their medical records, and failed to provide a telephone number of a California pharmacist in violation of CCR, title 16, Section 1707.2, subdivision (b)(2), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Failing to Dispense Medications in Properly Labeled Containers)

53. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that Respondents dispensed medications in improperly labeled containers, in violation of Code Section 4076, subdivision (a), as set forth in paragraphs 27 to 43, which are incorporated here by this reference, and as follows:

a. Respondents shipped prescriptions with the name DailyMed California on the boxed containers and shipping labels, and the name DailyMed Carlsbad on the prescription strip labels; and

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b. Respondents SavOn.com and Brown dispensed a prescription by affixing a prescription label on a box of Cyclosporin 100 mg capsules for a patient that identified the manufacturer as Watson but was manually changed to Teva, without the capsule identification being changed. The resultant prescription label identified the capsules as oblong shaped, off-white in color, inscribed PA20 from Watson, but the label was affixed to the Teva box of Cyclosporin 200 mg capsules which identified the capsules as an oblong shaped, brown capsule, inscribed with a logo and 100 mg.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Failing to Dispense Medications in Child-Resistant Containers)

54. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that on June 14, 2011, Respondents dispensed medications in non-child resistant packaging without proper authorization or warning, in violation of CCR, title 16, Section 1717, subdivision (a), and CFR, title 16, section 1701.1, as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

TWELFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Engaging in Fraud, Dishonesty, Deceit or Corruption)

55. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (f) in that Respondents engaged in acts involving moral turpitude, dishonesty, fraud, deceit, or corruption as set forth in paragraphs 27 to 43, which are incorporated here by this reference, and as follows:

a. By illegally wholesaling dangerous drugs in violation of California Code of Regulations section 1783, subdivision (d); and

b. By illegally operating DailyMed California, an unlicensed pharmacy, at Respondent SavOn.com's licensed pharmacy location in violation of Code Section 4110(a).

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THIRTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Illegal Transfers of Schedule II Controlled Substances)

56. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that Respondents transferred Schedule II controlled substances to DailyMed California, an unlicensed pharmacy, in violation of Code section 4169, subdivision (a)(1), and without completing and retaining DEA Form 222 in violation of CFR, title 21, section 1305.13, as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by Respondents SavOn.com and Brown – Illegal Transfers of Schedule III, IV and V Controlled Substances)

57. Respondents SavOn.com and Brown are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) in that Respondents transferred Schedule III, IV and V controlled substances to DailyMed California, an unlicensed pharmacy, in violation of Code section 4169, subdivision (a)(1), and without maintaining records concerning the number of commercial containers distributed, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed in violation of CFR, title 21, section 1304.22, subdivision (a)(2)(vii), as set forth in paragraphs 27 to 43, which are incorporated here by this reference.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy License No. PHY 48198 issued to SuperValu, Inc., d.b.a. Savon.com #5805;

2. Revoking or suspending Pharmacist License No. RPH 32935 issued to Perry Wayne Brown;

3. Ordering Supervalu, Inc., d.b.a. Savon.com #5805, and Perry Wayne Brown to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Taking such other and further action as deemed necessary and proper.

DATED: 2/17/14

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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